

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESale PRICE)	
LITIGATION)	MDL No. 1456
_____)	Civil Action No. 01-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	Hon. Patti B. Saris
)	
<i>United States of America ex rel. Ven-a-Care of</i>)	Magistrate Judge Marianne Bowler
<i>the Florida Keys, Inc. v. Abbott Laboratories,</i>)	
<i>Inc.,</i>)	
CIVIL ACTION NO. 06-11337-PBS)	

**MEMORANDUM BY THE UNITED STATES IN
RESPONSE TO ABBOTT LABORATORIES INC.'S OBJECTIONS TO THE
MEMORANDA AND ORDERS BY THE SPECIAL MASTER**

This memorandum responds to the objections by Abbott Laboratories Inc. (Abbott) to the memoranda and orders of the Special Master following his review of privileged documents submitted *in camera* by the United States (Dkt. 6260). The Court should overrule Abbott's objections because the Special Master's rulings are entirely consistent with prior orders and holdings by this Court. The Special Master was given ample briefing concerning the issues in this litigation and the potential relevance, or lack thereof, of the material which he was assigned to review. Accordingly, the assertion at the core of Abbott's objections, that his holdings were somehow uninformed, has no merit.

Since the very first month of discovery in this case, Abbott has directed considerable energy attacking the Government's assertion of deliberative process privilege. Lacking from Abbott's Objection brief, however, is any particularized discussion of how the Court has ruled on Abbott's previous motions and objections over the last two and a half years or the principles

set out by the Court with respect to the type of material that the Court would even consider requiring the Government to submit for *in camera* review, much less produce to defendants.

I. BACKGROUND

A. Prior Rulings by the Court - Scope of Discoverable Material

Abbott has filed no fewer than 22 briefs assailing the Government's assertion of the deliberative process privilege.¹ In ruling on Abbott's repetitive motions, the Court has found that only a limited class of material in the Government's files was even discoverable. For example, with respect to documents from CMS's Office of Legislation and Rulemaking Support Files – the two primary sources at CMS of deliberative material – the Court directed only that the Government review the files from these sources “for documents relating to Abbott's marketing the spread or the drugs at issue in this litigation.” Docket Order of Mar. 12, 2008. During subsequent hearings in these cases, the Court marginally expanded the scope of the material that the Government should either produce or submit *in camera* to include documents which relate to mega-spreads for “inhalants” and “infusion drugs,” the antibiotic Vancomycin, or the issue of “cross-subsidization.”² Abbott vigorously argued that cabining the Government's search obligations in this manner would deny Abbott access to a broader class of purportedly relevant policy-making material (*see, e.g.* Dkt. 4698 at 18). The Court rejected that argument,

¹ *See* Dkts. 3513, 3594, 3960, 4474, 4698, 4722, 4791, 4890, 4892, 4901, 5049, 5115, 5151, 5173, 5256, 5287, 5343, 5456, 5676, 5740, 5813, 5867.

² The Court addressed the scope of review for material from the Office of Legislation and Rulemaking Support Files at two hearings, one on July 24, 2008, the second on November 13, 2008. Copies of the hearing transcripts can be found at Dkt. 5847, Exhibits 1 and 2. Pertinent transcript sections are: Ex. 1 at 20:10-11, 23:19-24:14, Ex. 2 at 26:15-29, 27:7-8.

ruling that the Government should produce or submit *in camera* documents which fell within the parameters noted above. *See, e.g.*, Dkt. 4885.

B. The *In Camera* Submissions by the United States and the Parties’
Briefing of the Special Master

During a November 13, 2008 status conference, the Court directed the Government to review documents selected by the defendants from entries on the Government’s privilege logs and determine whether it would continue to assert privilege for all the documents. Defendants had been seeking judicial review of 184 documents, but – pursuant to the Court’s directive – the Government reviewed the documents and elected to release the majority of the documents designated by defendants. On December 8, 2008, the Government submitted 75 documents to the Court – 18 documents from the files of the Centers for Medicare and Medicaid Services (CMS), and 57 documents from the files of the Office of Inspector General for the Department of Health and Human Services (OIG).

Magistrate Judge Bowler referred consideration of the *in camera* submission to a Special Master. In addition to the documents that were in the Government’s December 8, 2008 *in camera* submission, pursuant to the Magistrate Judge’s Order, the Government also submitted to the Special Master documents from two prior *in camera* submissions (made in December 2007 and June 2008) as well as certain documents corresponding to entries on the Government’s privilege logs for documents withheld from production by Medicare Carriers. Finally, the Government also acceded to a request from Abbott counsel and submitted to the Special Master full versions of documents which had been released to defendants in redacted form. *See* May 1, 2009 Ltr. from J. Draycott to Hon. Allen van Gestel (Dkt. 6260, Ex. F).

Defendants provided the Special Master with binders of briefs and Court decisions drawn from the docket in this case. In total, the special master was given thirteen defense briefs, nine

Government briefs, two hearing transcripts, and five memoranda/orders by the District Court and Magistrate Judge. In total, defendants provided the special master with over 1300 pages of briefing material. Additionally, both Abbott and the United States provided further information and argument to the Special Master via briefing letters.

For the most part, the documents submitted to the Special Master were designated by defendants based on entries in the Government's privilege logs. The Government first began producing privilege logs in this MDL in connection with its 2004 subpoena production - that is before it was even a party to this proceeding, and then continued producing logs on a rolling basis over the course of discovery in these *qui tam* cases. Accordingly, the Government's privilege logs cover a range of material substantially broader than that deemed potentially discoverable by Judge Saris in rulings on motions to compel and during oral hearings in the later half of 2008.

II. ARGUMENT

The Orders of the Special Master may be overturned only if they are clearly erroneous. Per stipulation of the parties and with consent of the Court, for the purposes Fed. R. Civ. P. 53(f), decisions of the Special Master in this case are deemed final as if made by the Magistrate Judge.³ 28 U.S.C. § 636(b)(1). The First Circuit "regard[s] the existence of a privilege as a factual determination for the trial court, [therefore a] finding of no privilege can be overturned only if clearly erroneous." *Texaco P.R., Inc. v. Dept. of Consumer Affairs*, 60 F.3d 867, 883 (1st

³ The controlling Case Management Order appointing the Magistrate Judge gave her authority "for case management and all non-dispositive matters." Dkt. No. 756 at 1. Federal Rule of Civil Procedure 72(a) states in pertinent part: "When a pretrial matter not dispositive of a party's claim or defense is referred to a magistrate judge to hear and decide" upon appeal "[t]he district judge in the case must...modify or set aside any part of the order that is clearly erroneous or contrary to law."

Cir. 1995) (citing *United States v. Wilson*, 798 F.2d 509, 512 (1st Cir.1986)); accord *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 27 (1st Cir. 1989)

(“determination regarding the existence of a privilege is factual in nature”).

A. None of the Documents for which Abbott Seeks Judicial Review Is of a Type Which the Court Has Deemed Potentially Discoverable

Although the objections lodged against the decisions of the Special Master are not well-founded, Abbott can at least be credited with being candid with respect to its overriding grievance in this case. The opening line of Abbott’s argument states: [t]he deliberative process privilege has no place in this case...” Dkt. 6260 at 7. This statement is a *verbatim* recitation of the argument stated by Abbott in December 2006 when it lodged its first challenge to the Government’s assertion of the deliberative process privilege in this matter. Dkt. 3512 at 1 (“The deliberative process privilege . . . has no place in this case.”). After firing its opening salvo over two and half years ago, Abbott has relentlessly pursued this argument over the course of 22 ensuing briefs assailing the Government’s assertion of the deliberative process privilege. *See* fn. 1, *supra*. What Abbott’s latest objections ignore, most fundamentally, is that this argument has been rejected by the Court. The Court has indisputably found that the deliberative process privilege has a place in this case, that it will consider a privilege challenge by Abbott only with respect to relatively narrow categories of material, and in many instances has found that the Government’s interest in maintaining the confidentiality of deliberative documents outweighs defendants’ purported need for the material. If, as Abbott contends, the deliberative process privilege has no place in this case, there would have been no point to the *in camera* submissions required by the Court and the Magistrate Judge’s appointment of a Special Master would have been a waste of time for all concerned.

Second, Abbott's objections fail to take into account the principles articulated by the Court during oral hearings and in written orders addressing the Government's privilege assertions and to analyze whether the Special Master deviated from those principles. In terms of the types of material that may be deemed potentially discoverable, the Court directed that the Government search for documents that reflected knowledge of (1) mega-spreads for inhalants, infusion drugs, the antibiotic vancomycin, and/or defendants' drugs, (2) the issue of "cross subsidization," and (3) defendants' marketing of the spread associated with inflated AWP's, and that the Government either produce the documents to defendants or submit them to the Court *in camera*.

Throughout this litigation, Abbott has vigorously opposed parameters established by the Court. For example, with respect to the specification initially implemented by Magistrate Bowler that the Government produce just those documents referencing defendants' products, Abbott complained that this limitation would mean that policy-making documents would not be produced because it is unlikely that this type of material would make reference to particular manufacturers. Dkt. 4698 at 18. The District Court overruled Abbott's objections and retained the particularized limitation crafted by the Magistrate Judge (but amended the Magistrate's direction that Abbott-specific documents be produced directly to defendants and instead required that they be submitted to the Magistrate *in camera*). *See* Dkt. 4885 (requiring submission of "documents which relate to [the Government's] knowledge of a 'spread' for Abbott's drugs at issue in this litigation or its knowledge of Abbott's 'marketing the spread' for any of its drugs"). The Court later slightly expanded this parameter to include the categories of material described above. *See* fn. 2, *supra*.

With respect to its latest objections, Abbott simply ignores the decisional record in this case. Abbott has requested the Court review documents from six “substantive categories.” Dkt. 6260 at 11. Abbott’s categories, however, do not correspond to those established with precision, and after considerable deliberation, by the Court. Indeed, Abbott’s objections are not based upon any failure by the Special Master to order production of mega-spread documents for inhalant or infusion drugs. Rather, Abbott takes issue with the fact that he did not order the production of documents which Abbott considers potentially relevant to much broader issues. According to Abbott, documents reflecting “CMS’s understanding of how the industry as a whole, including drug manufacturers, understood the term ‘average wholesale price,’ is also quite relevant.” Dkt. 6260 at 12. Neither the Magistrate Judge nor the District Court have ever adopted this broad conception of relevance in resolving any of the repeated motions to compel by Abbott.

In light of this record, Abbott’s objections are not really about whether the Special Master applied the holdings and directions of the District Court when reviewing the documents, but rather are an attempt to re-litigate core issues relating to the Government’s privilege assertions that have already been decided by the Court.

B. The Special Master Did His Job

Magistrate Judge Bowler appointed the Honorable Alan van Gestel (retired) as a Special Master in this case on March 30, 2009. Abbott sent the Special Master the compilation of briefing materials on April 9, 2009. Counsel for all parties conferred via teleconference with the Special Master on April 22, 2009. On May 1, 2009, the Government submitted *in camera* the bulk of the material covered by Judge Bowler’s appointment order – and provided a few pages of

additional material later in the same month. Judge van Gestel issued his initial Memorandum and Order on June 22, 2009 - which was followed by a supplemental Memorandum on June 29, 2009.

On its face, the Memorandum and Order by Judge van Gestel demonstrates that he had read and digested the substantial briefing package submitted by Abbott. *See* Mem Order at 1-2 (Dkt. 6260, Ex. A). The Special Master also stated that he had read the Court's November 5, 2008 Order regarding the deliberative process privilege and "consider[ed] himself bound by the principles recited in Judge Saris's Order by which [his] *in camera* review [was] conducted." *Id.* at 3. The Special Master's Memorandum then sets out a concise and accurate summary of the controlling legal principles. *Id.* at 3-5. Abbott's objections do not appear to take issue with this part of the Special Master's memorandum. The Special Master further notes that he had conducted an individualized review of the *in camera* material. *Id.* at 5. He then demonstrates the truth of that statement by describing the documents in detail and explaining his reasons for (for the most part) not ordering the release of the documents. *Id.* at 5-16. While Abbott characterizes Judge van Gestel's comment that he was engaged in a "dense project" in a "complex case" as "troubling" (Dkt 6260, at 6), fairly read, this dicta is anything but troubling. To the contrary, the expression of this sentiment by a jurist exposed to this litigation for the first time should engender confidence in his conclusions given that he got it exactly right - the issues in these cases, and the broader MDL, are very complex. It would be troubling if the Special Master had failed to recognize the fundamental character of his assignment or had oversimplified the subject matter of this case.

In light of the actual text of the Special Master's decisions, Abbott's core argument, that he "simply accepted the Government's assertion that ... documents were irrelevant" (*id.*), is

patently incorrect. Plainly, the Special Master reviewed the substantial record transmitted by Abbott and then individually reviewed the documents submitted by the Government. Abbott simply disagrees with his conclusions. However, there was never a chance that Abbott would take any other position given that from the first month of discovery until now, it has persistently clung to the flawed premise that the deliberative process privilege “has no place in this case.”

Abbott also disputes the Special Master’s evaluation of the deliberative process privilege balancing test, which assesses a litigant’s need for privileged information. A litigant’s need, obviously and to a large extent, turns on the potential relevance of the evidence. Abbott continues to assail the Government’s reliance on *United States v. Lachman*, 387 F.3d 42 (1st Cir. 2004), which holds that informal opinions or statements by agency officials are not probative with respect to regulatory intent. Yet markedly absent from Abbott’s brief is citation to any language in *Lachman*, or any other case, indicating that pre-decisional draft material maintained in non-public files constitutes “agency guidance” that may be used as evidence of regulatory intent or underlying agency policy. Abbott has utterly failed to make a showing that the Special Master’s conclusions regarding the irrelevance of the material sought by Abbott are erroneous.⁴

C. The Few Documents Withheld from Production Based on Attorney Client Privilege or Work Product Doctrine Are Both Privileged and Irrelevant

⁴ The Court now has been briefed on the lack of relevance of the type of information sought by Abbott, which Abbott seeks in furtherance of its government knowledge and scienter defenses. As set forth in the United States’ Memorandum in Opposition to Defendants’ Motions for a Finding of Spoliation and for Sanctions (Dkt. 6270) and as set forth in the United States’ Memorandum of law in Support of Cross-Motion for Partial Summary Judgment and in Opposition to Abbott Laboratories Inc.’s Motion for Summary Judgment (Dkt. 6319), Abbott cannot meet any of the elements of a government knowledge defense.

Abbott asserts that the Government has waived attorney-client privilege and work product protection for four particular documents because entries on the Government's privilege logs for these documents reference only the deliberative process privilege. Abbott's argument appears to be premised on the assertion that the Government should have asserted the other privileges while fact discovery was still on-going and pursuant to the terms of the pertinent Case Management Order, which requires the issuance of a privilege log within 30 days of the document production from which privilege material was withheld. At this point in the MDL, the Government has been producing documents for over five years. In addition to the pre-intervention production that began in July 2004, in February 2007, the Government began a rolling production of documents in response to Rule 33 requests by defendants in these cases. The Government substantially completed its productions to defendants by the end of April 2008, which was the close of fact discovery in the Abbott case, and issued all its privilege logs before the close of fact discovery in the Abbott case.⁵

To the extent that Abbott is asking the Court to find waiver in this situation, such a holding by the Court would have vastly greater impact on Abbott's withholding of documents in light of its almost complete failure to log privileged material pursuant to the requirements of the CMO. Prior to April 2008, Abbott had provided an initial log with just a few entries. At the

⁵ In March 2005, the Government issued a privilege log for documents withheld from its pre-intervention MDL subpoena productions. Thereafter, Government began reviewing and refining the privilege assertions relating to the subpoenaed material. For example, in February 2007, the Government reviewed the privilege assertions, produced material withheld from the subpoena productions, and issued a revised log. After discovery in the intervened cases began, the Government produced privilege logs in conjunction with its rolling production of documents – as required by the governing Case Management Order. The Government began issuing amended or supplemental logs in February 2007, and produced eight additional logs on a rolling basis over the ensuing thirteen months.

very close of enlarged discovery, on April 25, 2008, Abbott provided its second amended privilege log detailing 749 total entries. After discovery closed, Abbott submitted its third and fourth amended privilege logs which added more than 243 new entries, for a total of 992 entries. If the Court is inclined to find privilege waiver for *four* Government documents, it should in the same order find that Abbott waived privilege for 243 additional documents based on its failure to produce logs for those documents before the close of discovery or in the time frame set out in the Case Management Order.

III. CONCLUSION

Based on the foregoing, the United States respectfully requests that the Court overrule Abbott's Objections to the Memoranda and Orders of the Special Master.

Respectfully submitted,

For the United States of America,

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Dated: August 11, 2009

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above MEMORANDUM BY THE UNITED STATES IN RESPONSE TO ABBOTT'S OBJECTIONS TO THE MEMORANDA AND ORDERS BY THE SPECIAL MASTER to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: August 11, 2009

/s/ Justin Draycott

Justin Draycott